

REMARKS

Claims 1-7 are pending. Claims 1-7 are under examination. Reexamination and reconsideration of the pending claims as amended in light of the following remarks is respectfully requested.

I. AMENDMENTS

Claims 1-7 have been amended. Independent claims 1 and 4 have been amended to recite the language "*and wherein said RIAA and IAA individually comprise at least 0.1% of the composition*". Support for these amendments is found in the Application as filed at Table 2, and paragraphs [0045] and [0059].

Independent claims 4 and 7 have been amended to introduce the language "*for reducing PGE₂ mediated inflammation*." Support for these amendments may be found in the specification as filed at Table 2, paragraphs [0045] and [0059] and in Examples 1 - 4.

Claims 2, 3, and 5 have been amended to insert a typical Markush grouping and improve claim form. Claim 3 has been amended to correct a much regretted typographical error. Claims 5 and 6 were amended to correct an improper dependency. These amendments are introduced to improve claim form and do not introduce new matter.

Accordingly, these amendments do not raise an issue of new matter and entry thereof is respectfully requested.

II. CLAIM OBJECTIONS

Claims 5, 6 have been objected insofar as they should depend on claim 4 and not on claim 1 (see page 2 of the Office Action). Claims 5 and 6 have been amended thereby addressing these objections. Withdrawal of these objections is thus, respectfully requested in light of these amendments.

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III. REJECTIONS UNDER 35 U.S.C. § 112

Claims 4-7 are rejected under 35 U.S.C. § 112, first paragraph, on the basis that *“the specification, while being enabling for a method of reducing inflammation by inhibiting COX-2 synthesis of PGE₂, does not reasonably provide enablement for reducing any inflammation.”* (see Office Action at page 2, emphasis in the original).

Claims 4 and 7 have been amended to conform with the Examiner’s finding that the specification is enabling for a method of reducing inflammation by inhibiting COX-2 synthesis of PGE₂ (see *supra*). Accordingly, claims 4 and 7 now specifically recite methods for the reduction of PGE₂ mediated inflammation.

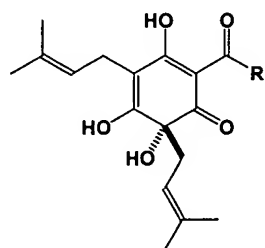
In light of the new recitation bringing the claims in conformance with the Examiner’s finding, Applicants respectfully ask for the withdrawal of these rejections and the reconsideration of the underlying claims.

Claims 1, and 4 stand rejected under 35 U.S.C. § 112, second paragraph, *“as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention”* (see the Office Action at page 7). Essentially, the phrases “reduced isoalpha acid” and “isoalpha acid” have been held to render the claims indefinite, in that it is not clear what other compounds the phrases encompass, since one of ordinary skill in the art would not ascertain the metes and bounds as to “reduced isoalpha acid” and “isoalpha acid”.

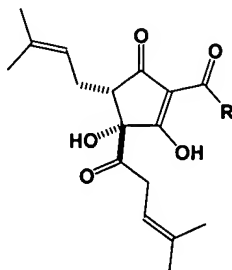
It is noted that the Examiner has stated that Applicants’ insertion of the chemical structures for reduced isoalpha acid and isoalpha acid would be favorably considered (see Office Action at page 7). Applicants kindly direct the Examiner’s attention to Figure 2 of the Application as filed where the chemical structures for reduced isoalpha acid and isoalpha acid are shown. The terms “reduced isoalpha acid” and “isoalpha acid” are well understood by those of ordinary skill in the art (see e.g., M. Verzele, D. De Keukeleire, Chemistry and Analysis of Hop and Beer Bitter Acids, Elsevier Publishing Company (1991)).¹

¹ See also, <http://www.ibd.org.uk/igbsite/business/training/files/Timscourses/tech%20Summ.%20Jan%2003.pdf>, and http://www.nysaes.cornell.edu/fst/faculty/acree/fs430/notes_siebert/kjs03hops.html.

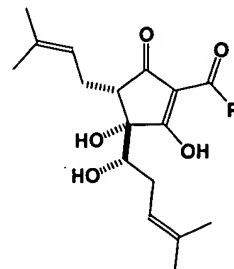
Hence, as understood by those of skill in the art, the terms "reduced isoalpha acid" and "isoalpha acid" are represented by the chemical structures provided herein below.



alpha



iso-alpha



reduced iso-alpha

humulone: $R = \text{CH}_2\text{CH}(\text{CH}_3)_2$

cohumulone: $R = \text{CH}(\text{CH}_3)_2$

adhumulone: $R = \text{CH}(\text{CH}_3)\text{CH}_2\text{CH}_3$

In light of these remarks Applicants kindly request withdrawal of this rejection in light of the examples presented *supra*.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." The phrase "wherein R is alkyl" has been found to render the claim indefinite, "as it is not clear what other compounds this phrase encompasses, since one of skill in the art would not ascertain the metes and bounds as to "wherein R is alkyl"" (see Office Action at page 7).

Applicants respectfully traverse this rejection. Applicants submit that "wherein R is alkyl" is not indefinite in that term "alkyl", as defined in any introductory chemistry text (see e.g., R. T. Morrison, R. N. Boyd, Organic Chemistry, Allyn and Bacon, Inc. (1983), Attachment A), refers to those substituents defined as $\text{C}_n\text{H}_{2n+1}$.

In light of the above remarks, Applicants aver that the term is understood in the art and is not indefinite. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

IV. REJECTIONS UNDER 35 U.S.C. § 103(A)

Claims 1-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuhrts (US 2004/0137096). Claims 1-7 are also rejected under 35 U.S.C. § 103(a) as being unpatentable over Tobe (US 5,604,263). Finally, Claims 1-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuhrts (US 2002/0086070). Applicants' remarks to these three rejections overlap. These three rejections are therefore taken together.

In each instance, the Examiner has opined that it would have been obvious to one of ordinary skill in the art to take the teachings cited and to determine the effective amounts of reduced isoalpa acid and isoalpa acid to arrive at the instant invention. The Applicants respectfully disagree.

Applicants submit that the instant invention is not obvious in light of the cited art in that the instant invention does not teach merely "effective amounts" of reduced isoalpa acid and isoalpa acid. The instant invention does not merely provide effective amounts of the active ingredients. The Application identifies certain ratios having qualities (foremost synergy) not previously known or suspected. The compositions and methods of the invention stem from the identification of **synergistic ratios** of reduced isoalpa acid and isoalpa acids which are neither taught nor suggested by the art cited.

As such, the Applicants respectfully aver the instant case is distinct and not obvious over the cited references and respectfully request withdrawal of these rejection under 35 U.S.C. § 103(a).

V. PROVISIONAL TYPE DOUBLE PATENTING REJECTIONS

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-115 of copending U.S. Patent Application Serial No. 10/464,410.

Claims 4-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending U.S. Patent Application Serial No.10/464,834.

Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending

U.S. Patent Application Serial No.10/689856, and over claims 1-6 of copending U.S. Patent Application Serial No.10/774,048.

It is noted that no claims have been allowed in this case yet. Applicants traverse the above recited rejections and courteously request that such rejections be held in abeyance pending the allowance of any of the underlying claims. At that time, Applicants shall address these rejections with specificity.

VI. EXAMINER'S NOTE

As to the Examiner's note found at page 12 of the Office Action, Applicants note that claims 1, 4, and 7 have been amended to incorporate the limitation "*and wherein said RIAA and IAA individually comprise at least 0.1% of the composition.*" This limitation places the compositions of the instant application outside the scope of beer and natural product hops, in so far as the amounts of RIAA in both beer and natural hops, or hops products is below 0.1%.

CONCLUSION

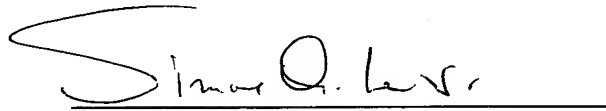
In light of the amendments and remarks herein, Applicant submits that the claims are now in condition for allowance and respectfully requests a notice to this effect. The Examiner is invited to contact the undersigned if there are any questions.

A Request for a Three (3) Month Extension of Time, up to and including November 4, 2005 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133.

<< CONT'D ON THE NEXT PAGE >>

Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under § 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectfully submitted,
MCDERMOTT WILL & EMERY LLP

A handwritten signature in black ink, appearing to read "Simona A. Levi-Minzi", is written over a horizontal line.

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MIA 301897-1.068911.0075

ATTACHMENT A

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U.S.S.N. 10/789,814

ATTACHMENT A to the Response to Office Action Pursuant to 37 C.F.R. § 1.111 filed on
November 4, 2005

Organic Chemistry

Fourth Edition

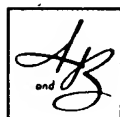
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Prefa

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2. Meth

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Table 3.2 NAMES OF ALKANES

CH ₄	methane	C ₉ H ₂₀	nonane
C ₂ H ₆	ethane	C ₁₀ H ₂₂	decane
C ₃ H ₈	propane	C ₁₁ H ₂₄	undecane
C ₄ H ₁₀	butane	C ₁₂ H ₂₆	dodecane
C ₅ H ₁₂	pentane	C ₁₄ H ₃₀	tetradecane
C ₆ H ₁₄	hexane	C ₁₆ H ₃₄	hexadecane
C ₇ H ₁₆	heptane	C ₁₈ H ₃₈	octadecane
C ₈ H ₁₈	octane	C ₂₀ H ₄₂	eicosane

The student should certainly memorize the names of at least the first ten alkanes. Having done this, one has at the same time essentially learned the names of the first ten alkenes, alkynes, alcohols, etc., since the names of many families of compounds are closely related. Compare, for example, the names *propane*, *propene*, and *propyne* for the three-carbon alkane, alkene, and alkyne.

But nearly every alkane can have a number of isomeric structures, and there must be an unambiguous name for each of these isomers. The butanes and pentanes are distinguished by the use of prefixes: *n*-butane and *isobutane*; *n*-pentane, *isopentane*, and *neopentane*. But there are 5 hexanes, 9 heptanes, and 75 decanes; it would be difficult to devise, and even more difficult to remember, a different prefix for each of these isomers. It is obvious that some systematic method of naming is needed.

As organic chemistry has developed, several different methods have been devised to name the members of nearly every class of organic compounds; each method was devised when the previously used system had been found inadequate for the growing number of increasingly complex organic compounds. Unfortunately for the student, perhaps, several systems have survived and are in current use. Even if we are content ourselves to use only one system, we still have to understand the names used by other chemists; hence it is necessary for us to learn more than one system of nomenclature. But before we can do this, we must first learn the names of certain organic groups.

3.8 Alkyl groups

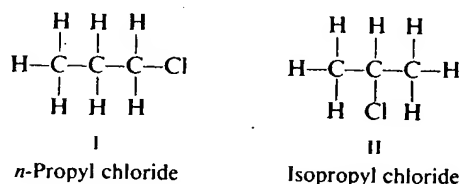
In our study of inorganic chemistry, we found it useful to have names for certain groups of atoms that compose only part of a molecule and yet appear many times as a unit. For example, NH_4^+ is called *ammonium*; NO_3^- , *nitrate*; SO_3^{--} , *sulfite*; and so on.

In a similar way names are given to certain groups that constantly appear as structural units of organic molecules. We have seen that chloromethane, CH_3Cl , is also known as *methyl chloride*. The CH_3 group is called **methyl** wherever it appears, CH_3Br being *methyl bromide*; CH_3I , *methyl iodide*; and CH_3OH , *methyl alcohol*. In an analogous way, the C_2H_5 group is **ethyl**; C_3H_7 , **propyl**; C_4H_9 , **butyl**; and so on.

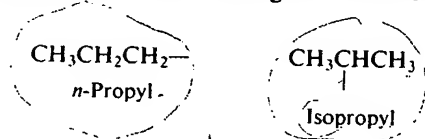
These groups are named simply by dropping *-ane* from the name of the corresponding alkane and replacing it by *-yl*. They are known collectively as **alkyl groups**. The general formula for an alkyl group is $\text{C}_n\text{H}_{2n+1}$, since it contains one less hydrogen than the parent alkane, $\text{C}_n\text{H}_{2n+2}$.

Among the alkyl groups we again encounter the problem of isomerism. There

is only one methyl chloride or ethyl chloride, and correspondingly only one methyl group or ethyl group. We can see, however, that there are two propyl chlorides, I and II, and hence that there must be two propyl groups. These groups both contain

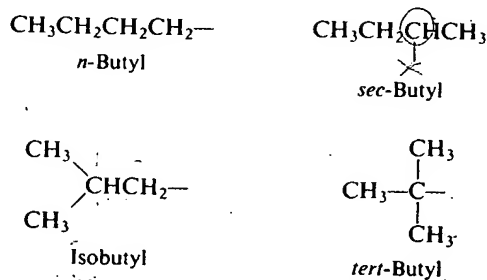


the propane chain, but differ in the point of attachment of the chlorine; they are called *n*-propyl and isopropyl. We can distinguish the two chlorides by the names



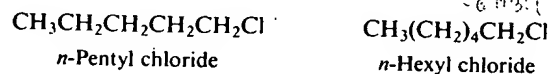
n-propyl chloride and isopropyl chloride; we distinguish the two propyl bromides, iodides, alcohols, and so on in the same way.

We find that there are four butyl groups, two derived from the straight-chain *n*-butane, and two derived from the branched-chain isobutane. These are given the designations *n*- (normal), *sec*- (secondary), *iso*-, and *tert*- (tertiary), as shown below. Again the difference between *n*-butyl and *sec*-butyl and between isobutyl and *tert*-butyl lies in the point of attachment of the alkyl group to the rest of the molecule.



Beyond butyl the number of isomeric groups derived from each alkane becomes so great that it is impracticable to designate them all by various prefixes. Even though limited, this system is so useful for the small groups just described that it is widely used; a student must therefore memorize these names and learn to recognize these groups at a glance in whatever way they happen to be represented.

However large the group concerned, one of its many possible arrangements can still be designated by this simple system. The prefix *n*- is used to designate any alkyl group in which all carbons form a single continuous chain and in which the point of attachment is the very end carbon. For example:



The prefix *iso*- is used to designate any alkyl group (of six carbons or fewer)

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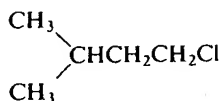
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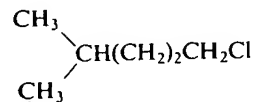
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that has a single one-carbon branch on the next-to-last carbon of a chain and has the point of attachment at the opposite end of the chain. For example:



Isopentyl chloride



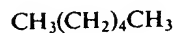
Isohexyl chloride

If the branching occurs at any other position, or if the point of attachment is at any other position, this name does not apply.

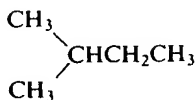
Now that we have learned the names of certain alkyl groups, let us return to the original problem: the naming of alkanes.

3.9 Common names of alkanes

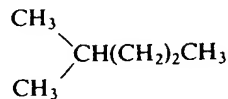
As we have seen, the prefixes *n*-, *iso*-, and *neo*- are adequate to differentiate the various butanes and pentanes, but beyond this point an impracticable number of prefixes would be required. However, the prefix *n*- has been retained for any alkane, no matter how large, in which all carbons form a continuous chain with no branching:

*n*-Pentane*n*-Hexane

An *isoalkane* is a compound of six carbons or fewer in which all carbons except one form a continuous chain and that one carbon is attached to the next-to-end carbon:



Isopentane



Isohexane

In naming any other of the higher alkanes, we make use of the IUPAC system, outlined in the following section.

(It is sometimes convenient to name alkanes as derivatives of methane; see, for example, I at the top of p. 137.)

3.10 IUPAC names of alkanes

To devise a system of nomenclature that could be used for even the most complicated compounds, various committees and commissions representing the chemists of the world have met periodically since 1892. In its present modification, the system so devised is known as the **IUPAC system** (International Union of Pure and Applied Chemistry). Since this system follows much the same pattern for all families of organic compounds, we shall consider it in some detail as applied to the alkanes.

Essentially the rules of the IUPAC system are:

1. Select as the parent structure the longest continuous chain, and then consider the compound to have been derived from this structure by the replacement

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